

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit: 1643
)	
KOGANTY, et al.)	Examiner: HOLLERAN, A.
)	
Serial No.: 10/511,101)	Washington, D.C.
)	
Filed: September 12, 2005)	February 13, 2008
)	
For: SYNTHETIC GLYCO-LIPO- PEPTIDES AS VACCINES)	Docket No.: KOGANTY=4A
)	Confirmation No.: 6156

INFORMATION DISCLOSURE STATEMENT [IDS] NO. 2

U.S. Patent and Trademark Office
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

☒ B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

☐ i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. A Credit Card Authorization, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Authorization, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[] A. Documents _____ are U.S. Patents or U.S. Patent Publications, and hence copies of these documents have not been provided. See 37 CFR 1.98(a)(2)(ii).

[] B. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

☐ 3. Documents _____ are not in the English language. In accordance with 1.98(a)(3), Applicants state:

☐ documents _____ already contain an English language abstract, summary or claim set.

☐ a publicly available abstract is attached to each of documents ____, and the source of each abstract is indicated thereon.

☐ documents _____ are publicly available English language abstracts of foreign language patents. If the Examiner would like us to obtain a copy of the underlying document, with or without a translation, s/he should contact Counsel.

☐ documents ____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

☐ applicants have prepared an English translation of at least the pertinent portions of documents _____, and copies are attached.

☐ A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _____ appears in the present specification.

[] A concise explanation of the relevance of documents _____ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

Price (Ref. CA) Table 4 discloses eight synthetic peptides, none of which were glycosylated or lipidated.

The 105-mer (Gr #14) and 100-mer (Gr #11) are said to represent 5 complete VNTR ("variable number of tandem repeat") units and thus each include five copies of

the sequence P(D/E)(T/S)RP. The sequence of the 25-mer (Gr-11) peptide is not stated; it would include two sequences P(D/E)(T/S)RP if and only if it ended with PDTRP. Since the 20-mer (Gr. 10) is said at page 10, col. 2 to begin with "PAHGV..." we assume that either the 25-mer begins the same way, or with "GSTAP" (the final pentapeptide of the 20-mer). Either way, it offers only one copy of PDTRP.

Table 4 summarized the reactivity of various anti-MUC1 antibodies with the aforementioned synthetic peptides.

The only antibodies reactive with the 100 mer, and not the 20 mer, are #132 (MF 30), #134 (BW 835), #149 (MF 11), #158 (M38), #162 (214 D4), #166 (12C10), #173 (BCRU-G7). However, #155 (Sec 1) and #174 (BCP10) are reactive with the 20 mer and not the 100-mer.

There are also differences in reactivity between the 105- and 100-mers.

The reference taught, "there was no relationship between peptide length and immunoreactivity (table 4)". The overall percent reactivity was 46% for the 105-mer, 64% for the 100-mer, 46% for the 25-mer, 55% for the 20-mer Gr #4, 60% for the (permuted) 20-mer Gr. 10, 31% for the 16-mer, 55% for the 9-mer, and 46% for the 7-mer.

Consequently, there would be no motivation to replace the BP1-219 (19 mer) and BP1-223 (18-mer) peptide sequences with a longer sequence such as D6's 100- or 105-mer sequences.

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing

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of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 

Iver P. Cooper
Reg. No. 28,005

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms
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